OFFICE of the INSURANCE COMMISSIONER
WASHINGTON STATE

Mike Kreidler- Insurance commissioner

As required by

The Washington State Administrative Procedures Act

Chapter 34.05 RCW

Matter No. **R2022-05**

CONCISE EXPLANATORY STATEMENT; RESPONSIVENESS SUMMARY; RULE DEVELOPMENT PROCESS; AND IMPLEMENTATION PLAN

Relating to the adoption of

Cost-Sharing for Prescription Drugs

November 1, 2022

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Section 1: Introduction

Revised Code of Washington (RCW) 34.05.325 (6) requires the Office of Insurance Commissioner (OIC) to prepare a “concise explanatory statement” (CES) prior to filing a rule for permanent adoption. The CES shall:

1. Identify the Commissioner's reasons for adopting the rule;
2. Describe differences between the proposed rule and the final rule (other than editing changes) and the reasons for the differences;
3. Summarize and respond to all comments received regarding the proposed rule during the official public comment period, indicating whether or not the comment resulted in a change to the final rule, or the Commissioner's reasoning in not incorporating the change requested by the comment; and
4. Be distributed to all persons who commented on the rule during the official public comment period and to any person who requests it.

Section 2: Reasons for Adopting the Rule

In 2022, the Washington State Legislature enacted Substitute Senate Bill 5610 (Chapter 228, Laws of 2022)—Prescription Drug Cost Sharing—Enrollee Contribution Calculation, now codified in RCW 48.43.435. SSB 5610 provides direction for applying payments to cost-sharing amounts and the out-of-pocket maximum, except in specified conditions. The rulemaking will provide consistency and transparency to enrollees using third party payment assistance. The definitions of cost sharing and out-of-pocket maximum are clarified to include coupons and carriers are required to provide enrollees disclosure of their benefits and appeal rights when third party payments are used

Section 3: Rule Development Process

On June 9, 2022, the Commissioner filed the notice of rulemaking (CR-101). Comments were accepted until July 15, 2022.

On June 30, 2022, a prepublication draft was posted on the OIC website and sent out via GovDelivery, with comments invited until July 15, 2022.

An interested parties meeting was held on July 12, 2022; a number of comments were received.

On August 23, 2022, the Commissioner filed the proposed rule (CR-102), with comments accepted through October 3, 2022.

The public hearing was held on September 28, 2022. Several interested parties were in attendance, a single person provided testimony. The hearing summary is in Appendix A.

Section 4: Differences Between Proposed and Final Rule

There are no differences between the proposed version that was submitted with the CR-102 and the adopted version.

Section 5: Responsiveness Summary

The OIC received comments and suggestions regarding this rule. The following information contains a summary of the comments, the OIC's response to the comments, and information about whether the OIC incorporated changes based on the comments.

The OIC received comments from:

- America's Health Insurance Plans
- Cambia
- Coordinated Care
- Kaiser Permanente
- Northwest Health Law Advocates
- Patient Coalition of Washington
- Pharmaceutical Care Management Association
- Pharmaceutical Research and Manufacturers of America

Comments to the CR-101, prepublication draft, and CR-102

General Comment	OIC Response
Prepublication Draft	
Therapeutic equivalent definition	
Recommend that OIC adopt a definition for "therapeutic equivalent" consistent with the U.S. Food and Drug Administration's definition under 21 C.F.R. § 314.3(b): Therapeutic equivalents are approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.	The OIC considered the recommendation, but determined it be beyond the Commissioner's scope of authority in this rulemaking.
Drug substitutions	
Concerned that "therapeutic class" may preclude use of preferred therapeutic equivalents "A carrier may design its prescription drug benefit to include cost control measures, including requiring preferred drug substitution ~~in a given therapeutic~~	Request is outside of the current rulemaking for implementation of SSB 5610 chapter 228 laws 2022. WAC 284-43-5080 (1) is the existing regulation.

~~class~~, if the restriction is for a less expensive, equally therapeutic alternative product available to treat the condition."	
WAC 284-43-5080 (4) This subsection currently states, "A carrier may require an enrollee to try an AB-rated generic equivalent or a biological product that is an interchangeable biological product prior to providing coverage for the equivalent branded prescription drug." Request incorporating biological product substitution into the SSB 5610 regulations.	Request is outside of the current rulemaking for implementation of SSB 5610 chapter 228 laws 2022.
Cost sharing	
Recommend revisions to WAC 284-43-5080(5)(a) to align with SSB 5610: (a) For the purposes of this subsection, **any** cost sharing **amount paid directly by or on behalf of the enrollee by another person for a covered prescription drug** ~~or out-of-pocket amounts include payments from all sources as though it was paid by the enrollee directly and~~	The Commissioner is accepting this change.
Clarify that payments are made to a pharmacy at the point-of-sale	The Commissioner has considered the request and has included language consistent with SSB 5610 and the final bill report that states the cost sharing applies at the time rendered. The proposed rule reflects this change.
HSA	
HSA-qualifying plans—high-deductible health plans IRS guidance: "Discount cards that entitle holders to obtain discounts for health care services or products at managed care market rates	After considering comments and the language of SSB 5610, the OIC has decided that regulations are not needed for additional clarification. The application of the manufacturer's coupon to cost sharing amounts must comply

will not disqualify an individual from being an eligible individual for HSA purposes if the individual is required to pay the costs of the health care (taking into account the discount) until the deductible of the HDHP is satisfied" Illinois DOI IRS April 2021 response: a deductible may only be satisfied by actual medical expenses the covered individual incurred. SSB 5610 language is carefully crafted Proposed regulatory language addresses the deductible itself, not the payments counted toward the deductible. To preserve an enrollee's health savings account (HSA) eligibility, high-deductible health plans can only cover preventative services without applying the deductible; all other services must meet the health plan's deductible first…. Inclusion of individual and family deductibles goes beyond the legislative intent Concern that the first sentence excludes all HSA plans. Understanding is that once the patient has paid the minimum deductible, defined by the IRS, the patient should be able to utilize third-party assistance towards their cost-sharing requirements, such as the rest of their deductible or any co-pays or co-insurance. Preferred Language: If under federal law, application of this requirement would result in Health Savings Account ineligibility under section 223 of	with the internal revenue service laws, regulations, and guidance and preserve the enrollee's ability to claim tax exempt contributions and withdrawals from their health savings account. Preventative care that is not subject to cost sharing would not be subject to this rule.

the federal Internal Revenue Code, this requirement shall apply for Health Savings Account-qualified High Deductible Health Plans with respect to the deductible of such a plan after the enrollee has satisfied the minimum deductible under section 223, except for with respect to items or services that are preventive care pursuant to section 223(c)(2)(C) of the federal Internal Revenue Code, in which case the requirements of this paragraph shall apply regardless of whether the minimum deductible under section 223 has been satisfied.	
Certification of coverage disclosures	
Clarify that carriers are not required to insert the exact language from the regulation or legislation into member booklets. Allow flexibility for carriers to adjust for reading level Recommend inclusion of notice with billing or evidence of benefits where annual accruals are list or/and pharmacies Language to adhere to "plain language" with verbatim notice for inclusion in their enrollee documents	The Commissioner revised the language in the proposed rule to clarify that carriers are not required to insert verbatim language from the statute or regulation into the member's evidence of coverage (also commonly referred to as the member booklet). The Commissioner has considered the request, but declines to require inclusion of a notice within billing statements or evidence of benefits as part of the proposed rule. The Commissioner always prioritizes transparency in consumer communications. The Commissioner has considered the comments about plain language and is declining to impose new standards at this time for the carriers' plan documents.

Subsection (5)(d) would be a disincentive to pharmaceutical manufacturers from negotiating the prices of their drugs down because it would allow enrollees (ie, insured individuals) the ability to double-dip not only by utilizing a manufacturer's patient assistance program by having any cost contributions count toward the cost-sharing under the terms of the enrollee's prescription drug benefits.	The Commissioner disagrees. SSB 5610 was enacted to provide the insured individuals access to the manufacturer's coupons where the drug is determinized to be medically appropriate and where preferred formulary substitutions were not indicated for the patient. The legislation was narrowed to apply only where there are not generic or preferred therapeutic equivalents for substitutions, or the enrollee has gained access through established utilization controls or the exceptions process.
Cost sharing during appeal	
Believe it is above the scope of SSB 5610 to require the cost-sharing requirements apply throughout the adverse benefit determination process –that process includes determinations that are outside of the drug exception request process.	Under current law, the appeals process for a denial of a prescription drug exception is the adverse benefit determination process WAC 284-43-2022 (6)
(5)(b) and (5)(d) leaves open the possible interpretation of no resolution nor finality should an enrollee be unsuccessful in seeking cost-sharing coverage under the terms of the enrollee's prescription drug benefits. Clarify that if an enrollee's request to an exception or an appeal of a denial of an exception request are unsuccessful that neither the PBM nor health carrier be responsible to apply any cost contribution made by the enrollee be applied toward the enrollee's cost-sharing for prescription drug benefits.	The Commissioner finds the request unnecessary. The law specifies coverage only during the time while appeals determinations are being made and that determination is communicated.
Proposed Rule	
Therapeutic equivalent definition	
WAC 284-43-5080 (1) – Prescription drug benefit design	WAC 284-43-5080 (1) is current law. SSB 5610 references substitutions for therapeutic equivalents. It is beyond the authority in this rulemaking to

requests that reference to the underlying statute, including the recently enacted bill language of SSB 5610, be included, to make any necessary distinctions needed between "therapeutic class" and "therapeutic alternative."	differentiate the terms "therapeutic class" and "therapeutic alternative."
HSA	
Currently, the Proposed Rule does not include any clarifying language with regard to potential issues arising for enrollees with a high-deductible health plan ("HDHP") and a health savings account ("HSA"). Requests that additional clarifying language be added to the Proposed Rule *Requested change in language:* If application of subparagraph a of this paragraph would result in health savings account ineligibility under Section 223 of the Internal Revenue Code, as amended, subparagraph a shall not apply to a qualified high deductible health plan with a health savings account. The language of the law makes it clear that the legislature intended this requirement to apply to health saving account—eligible high deductible health plans to the maximum extent possible. The rule should make clear that cost sharing amounts paid on behalf of an enrollee by another person must count toward applicable cost-sharing and out-of-pocket maximums when allowable for HSA-eligible HDHPs. Recommend aligning the health saving account eligible high--deductible health plans with the current federal Internal Revenue Service (IRS) guidance:	SSB 5610 codified at RCW 48.43.435(5) states: (5) This section does not apply to a qualifying health plan for a health savings account to *the extent necessary to preserve the enrollee's ability to claim tax exempt contributions and withdrawals* from the enrollee's health savings account under internal revenue service laws, regulations, and guidance. The law is sufficiently clear to address the application of cost sharing where an HSA is used to maintain tax exemption. The Commissioner agrees that the language of the law makes it clear that the legislature intended this requirement to apply to health saving account—eligible high deductible health plans to the maximum extent possible. And that cost sharing amounts paid on behalf of an enrollee by another person must count toward applicable cost-sharing and out-of-pocket maximums when allowable for HSA-eligible HDHPs The statute references internal revenue service laws, regulations, and guidance. That reference is intended to achieve compliance under the current section 223 of the federal Internal Revenue Code and after the enrollee has satisfied the minimum deductible under section 223

Requested change in language: If under federal law, application of this requirement would cause a Health Savings Account - qualified High Deductible Health Plan to fail to qualify as such a plan under section 223 of the federal Internal Revenue Code, this requirement shall apply with respect to such a plan after the enrollee has satisfied the minimum deductible under section 223, except for with respect to items or services that are preventive care pursuant to section 223(c)(2)(C) of the federal internal Revenue Code, in which case the requirements of this paragraph shall apply regardless of whether the minimum deductible under section 223 has been satisfied.	that SSB 5610 chapter 228 laws 2022 cost-sharing provisions apply. The Commissioner is not including the federal citations in the rule to allow for application of any additional federal rules or guidance that may later be adopted. Preventive care is not subject to cost sharing and thereby is not subject to the SSB 5610 chapter 228 laws 2022 cost sharing provisions.
Cost sharing during appeal	
In the context of a pending enrollee exception request or appeal of a denial, the language of the Proposed Rule does not align with how this process is operationalized by a pharmacy benefit manager ("PBM") or a health plan. Without an approved exceptions request, there would be no benefit coverage for the drug at issue. Thus, no cost-sharing. *Requested change in language:* (5)(b) be changed to remove any mention of "cost-sharing" and the delineation of the different types of cost-sharing, including, but not limited to: deductible, copayment, coinsurance, or out-of-pocket maximum. In our view, the exception request process, or an appeal of a denial of an exception request will only apply when these two elements are present: (a) the "prescription drug is a covered benefit"; and (b) "the enrollee is "currently receiving the prescription drug under review in the exception request process or appeal of a	SSB 5610 codified at RCW 48.43.435(1)(a)(iii) states: (iii) With a generic equivalent or therapeutic equivalent preferred under the health plan's formulary, throughout an exception request process under RCW 48.43.420, including any appeal of a denial of an exception request. If the health carrier utilizes a health care benefit manager to approve or deny exception requests, the exception request process for the purposes of this subsection *(1)(a)(iii) also includes any time between the completion of the exception request process, including any appeal of a denial, and when the health care benefit manager communicates the status of the request to the health carrier.* 5(b) is specific to clarifying that the cost sharing amounts reflect the benefits that an enrollee had prior to carrier's changes that initiated the enrollee's need to file an

denial". Thus, if the two elements stated above are absent, then until the health carrier approves/authorizes the prescription drug under the exception process, it's a non-covered benefit and as such any cost-sharing amount paid the enrollee directly or on behalf of the enrollee by another person must not count towards any applicable deductible, copayment, coinsurance, or out-of-pocket maximum.	exceptions request, as may occur in a formulary change: 5(b) If an enrollee requests an exception under RCW 48. 43. 420 or appeals a denial of an exception request, and the request or appeal is still pending, any amount paid by or on behalf of an enrollee for a covered prescription drug must be applied towards the enrollee's contribution to any applicable deductible, copayment, coinsurance, or out-of-pocket maximum until the review is resolved and the status of the request is communicated to the carrier.

Section 6: Implementation Plan

A. Implementation and enforcement of the rule.

Health carriers must provide disclosures to the enrollees regarding third-party payments and how such payments are applied to enrollee cost-sharing and the out-of-pocket maximum. The disclosure is to be included in the certificate of coverage (also commonly referred to as the member booklet or member handbook). The Rates, Forms, and Provider Networks Division (RFPN) will review plan language as part of its existing review and objection process for all nongrandfathered health plans with effective dates on or after January 1, 2023. RFPN will also provide instructions to health carriers for how to revise plan year 2023 forms that have already been reviewed and closed but are impacted by this rulemaking. Market Conduct Oversight Unit will review compliance based on complaints or concerns reported by the enrollees or other interested parties.

B. How the Agency intends to inform and educate affected persons about the rule.

After the agency files the permanent rule and adopts it with the Office of the Code Reviser, policy staff will distribute the final rule and the Concise Explanatory Statement (CES) to all interested parties by posting on the OIC website and sending it out to the rulemaking listserv.

OIC will address questions as follows:

Type of Inquiry	Division
Consumer assistance	Consumer Protection
Rule content	Policy and Legislative Affairs
Authority for rules	Policy and Legislative Affairs
Enforcement of rule	Legal
Market Compliance	Company Supervision

C. How the Agency intends to promote and assist voluntary compliance for this rule.

- Policy and Legislation Division staff will distribute the final rule and the Concise Explanatory Statement (CES) to all interested parties by posting and sharing the documents through the OIC's standard rule making listserv.
- The Rules Coordinator will post the CR-103 documents on the OIC's website.

D. How the Agency intends to evaluate whether the rule achieves the purpose for which it was adopted.

The OIC will continue to work with the carriers and interested parties regarding the requirements, as well as monitor consumer complaints and plans for non-compliance.

Appendix A

CR-102 Hearing Summary

Summarizing Memorandum

To: Mike Kreidler
Insurance Commissioner

From: Barb Jones
Presiding Official, Hearing on Rule-making

Matter No. R 2022-05

Topic of Rule-making: Cost Sharing for Prescription Drugs

This memorandum summarizes the hearing on the above-named rule making, held on September 28, 2022 at 9:00 in Olympia WA via zoom, over which I presided in your stead.

The following agency personnel were present:
Jesse Wolff
Deanna Ogo
Kimberly Tocco

In attendance and testifying:

Peter Fjelstad

In attendance NOT testifying:

Joe Baker
Jillian Caughey
Devon Connor-Green
Merlene Converse
Zachary Correia
Erica Diamantides
Erin Dziedzic
Carrie Glover
Seth Greiner
Frankie Kaiser
Eric Lohnes
Barbara Morrow
Dharia McGrew
LuGina Mendez-Harper

tonia neal
Margo Parks
Nealy Wilson
Condee Wood

Contents of the presentations made at hearing:

Appreciation for sharing prepublication draft and changes made in the proposed rule**.**

The legislation was intentionally negotiated and citation back to the statute, to ensure consistency with legislative intent, is requested.

SIGNED this 28th day of September,2022

s/
Barb Jones, Presiding Official